REMARKS

Claims 1-3 are pending in the instant application. Claims 1-3 have been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

Claims 1-3 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Coligan et al. (Current Protocols in Immunology, Green Publishing Associates and Wiley-Interscience, New York, 1991; pages 2.1.1-2.1.3, 2.1.9-2.1.11, and 2.1.17-2.1.22) in view of U.S. Patent 5,077,216, Zwaldo et al. (1987) (IDS Reference BA), and Zwaldo et al. (1992) (IDS Reference AX); and Hogger et al. ((1998) *Pharma. Res.* 15:296-302) as evidenced by Sulahian et al. ((Sept. 2000) *Cytokine* 12:1312-1321) for the reasons of record. Applicants respectfully disagree with this rejection for the reasons of record and the following.

Applicants respectfully maintain that, as a whole, the cited prior art references fail to teach or suggest the use of CD163 antigen (*i.e.*, RM3/1) for detecting an early signaling event in the inflammatory response cascade in a patient, specifically within 1 to 12 hours of exposure to the inflammatory stimulus. With regard to CD163 detection, the '216 patent teaches antibody recognition of p155 expressed on human monocytes, monocyte-derived macrophages and peritoneal macrophages, and Zwaldo et al. (1987), Zwaldo et al. (1992), and Hogger et al. (1998) teach expression of CD163 on human monocytes and macrophages during the down-regulatory or healing phase of the inflammation. In contrast, the experiments disclosed at pages 9-11 of the instant

specification demonstrate that "soluble CD163 is one of the earliest changes induced in an acute inflammatory response that can be detected in plasma" (see page 11, lines 11-13). The correlation between an increase in the shedding of CD163 from monocytes *in vivo* and early signaling events in an inflammatory response cascade is neither taught nor suggested by the prior art references. Accordingly, in an earnest effort to specify the nature of the CD163 being detected and advance the prosecution of this application, claim 1 has been amended to indicate the detection of *soluble* CD163 in a biological sample, wherein an elevated level of *soluble* CD163 within 1 to 12 hours of exposure to the inflammatory stimulus is indicative of an early signaling event in the inflammatory response cascade in a patient. Support for detecting soluble CD163 in a biological sample is found throughout the specification and in particular exemplified in the experimental analysis disclosed at pages 9-11. Because the cited prior art references fail to teach or suggest soluble CD163 detection, these references fail to teach or suggest all the claim limitations (see MPEP 2143). Thus, the cited reference cannot be held to make the present invention obviousness under 35 U.S.C. 103(a). It is therefore respectfully requested that this rejection be withdrawn.

II. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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